THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants:	Kuslys et al.
Appl. No.:	10/088,766
Conf. No.:	2286
Filed:	June 20, 2002
Title:	COMPOSITION COMPRISING CASEIN PROTEIN AND WHEY PROTEIN
Art Unit:	1645
Examiner:	J. Hines
Docket No.:	112701-780

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on October 21, 2008. This Appeal is taken from the Final Rejections in the Office Action dated July 14, 2008.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Nestec S.A. by virtue of an Assignment dated June 20, 2002 and recorded at reel 013035, frames 0768-0773 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 1, 3-4, 6-10 and 13-20 are pending in the above-identified patent application. Claims 2, 5 and 11-12 were previously canceled. Claims 1, 3-4, 6-10 and 13-20 stand rejected. Therefore, Claims 1, 3-4, 6-10 and 13-20 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Non-Final Office Action was mailed on January 16, 2008. In the Non-Final Office Action, the Patent Office maintained the previous ground of rejection under 35 U.S.C. §103. Appellants filed a response to the Non-Final Office Action on April 16, 2008. A Final Office Action was mailed on July 14, 2008. In the Final Office Action, the Patent Office maintained the obviousness rejection. Appellants filed a Notice of Appeal on October 21, 2008 with respect to the Final Office Action mailed on July 14, 2008. Copies of the Non-Final Office Action mailed on January 16, 2008 and the Final Office Action mailed on July 14, 2008 are attached as Exhibits A and B, respectively, in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 1 recites a composition for an infant formula (page 2, lines 6-11; page 4, lines 20-23; page 6, lines 32-35; page 7, lines 12-29) comprising: whey protein (page 2, lines 35-36; page 3, lines 1-9 and 24-29; page 4, lines 25-31; page 5, lines 21-25), wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed (page 2, lines 35-36; page 4, lines 33-36; page 5, lines 1-16); casein protein (page 2, lines 9-11 and 15-22; page 3, lines 29-32); free arginine (page 2, lines 15-22; page 3, lines 11-15 and 34; page 4, lines 1-8; page 5, lines 25-35; page 6, line 1); free histidine (page 2, lines 15-22; page 3, lines 11-15 and 34; page 4, lines 1-8; page 5, lines 25-35; page 6, line 1); and a milk protein comprising 5% or more of tryptophan (page 2, lines 15-22 and 32-33; page 4, lines 20-23).

Independent Claim 10 recites a method of producing an infant formula (page 2, lines 6-11; page 4, lines 20-23; page 6, lines 32-35; page 7, lines 12-29), the method comprising blending whey protein (page 2, lines 35-36; page 3, lines 1-9 and 24-29; page 4, lines 25-31; page 5, lines 21-25), wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed (page 2, lines 35-36; page 4, lines 33-36; page 5, lines 1-16), and casein protein (page 2, lines 9-11 and 15-22; page 3, lines 29-32) together with free arginine (page 2, lines 15-22; page 3, lines 11-15 and 34; page 4, lines 1-8; page 5, lines 25-35; page 6, line 1); free histidine (page 2, lines 15-22; page 3, lines 11-15 and 34; page 4, lines 1-8; page 5, lines 25-35; page 6, line 1); a milk protein comprising 5% or more of tryptophan (page 2, lines 15-22 and 32-33; page 4, lines 20-23) and homogenising the blended mixture (page 2, lines 19-22; page 8, lines 11-13).

Independent Claim 13 recites an infant formula (page 2, lines 6-11; page 4, lines 20-23; page 6, lines 32-35; page 7, lines 12-29) comprising: hydrolysed sweet whey protein, from which caseino-glyco-macropeptide has been removed (page 2, lines 35-36; page 4, lines 33-36; page 5, lines 1-16); casein protein (page 2, lines 9-11 and 15-22; page 3, lines 29-32); free arginine (page 2, lines 15-22; page 3, lines 11-15 and 34; page 4, lines 1-8; page 5, lines 25-35; page 6, line 1); free histidine (page 2, lines 15-22; page 3, lines 11-15 and 34; page 4, lines 1-8; page 5, lines 25-

35; page 6, line 1); and a milk protein comprising 5% or more tryptophan (page 2, lines 15-22 and 32-33; page 4, lines 20-23).

Independent Claim 20 recites a method of providing nutrition to an infant (page 1, lines 6-7; page 2, lines 28-30), the method comprising administering to the infant a composition comprising whey protein (page 2, lines 35-36; page 3, lines 1-9 and 24-29; page 4, lines 25-31; page 5, lines 21-25), wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed (page 2, lines 35-36; page 4, lines 33-36; page 5, lines 1-16); casein protein (page 2, lines 9-11 and 15-22; page 3, lines 29-32); free arginine (page 2, lines 15-22; page 3, lines 11-15 and 34; page 4, lines 1-8; page 5, lines 25-35; page 6, line 1); free histidine (page 2, lines 15-22; page 3, lines 11-15 and 34; page 4, lines 1-8; page 5, lines 25-35; page 6, line 1); and a milk protein comprising 5% or more of tryptophan (page 2, lines 15-22 and 32-33; page 4, lines 20-23).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the reference numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the reference numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1, 3-4, 6-10 and 13-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application No. 2003/0059501 A1 to Rivier ("*Rivier*") in view of International Patent Application No. WO 00/33854 A1 to De Jong et al. ("*De Jong*"). Copies of *Yonekubo* and *Georgi* are attached herewith as Exhibits C-D, respectively, in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARDS

Obviousness under 35 U.S.C. §103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made…The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art…Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness…Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Moreover, the Patent Office must provide explicit reasons why the claimed invention is obvious in view of the prior art. The Supreme Court has emphasized that when formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged

from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

Further, the Federal Circuit has held that it is "impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

B. THE CLAIMED INVENTION

Independent Claim 1 recites, in part, a composition for an infant formula. The composition comprises whey protein, casein protein, free arginine, free histidine, and a milk protein. The whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed. The milk protein comprises 5% or more of tryptophan.

Independent Claim 10 is directed to a method of producing an infant formula. The method comprises: (1) blending whey protein and casein protein together with free arginine, free histidine, and a milk protein; and (2) homogenising the blended mixture. The whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed. The milk protein comprises 5% or more of tryptophan.

Independent Claim 13 recites, in part, an infant formula. The infant formula comprises hydrolysed sweet whey protein, casein protein, free arginine, free histidine, and a milk protein. Caseino-glyco-macropeptide has been removed from the hydrolysed sweet whey protein. The milk protein comprises 5% or more of tryptophan.

Independent Claim 20 is directed to a method of providing nutrition to an infant. The method comprises administering to the infant a composition. The composition comprises whey protein, casein protein, free arginine, free histidine, and a milk protein. The whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed. The milk protein comprises 5% or more of tryptophan.

C. THE REJECTION OF CLAIMS 1, 3-4, 6-10 AND 13-20 UNDER 35 U.S.C. §103(a) TO *YONEKUBO* AND *GEORGI* SHOULD BE REVERSED BECAUSE THE PATENT OFFICE HAS NOT ESTABLISHED A *PRIMA FACIE* CASE OF OBVIOUSNESS

Appellants respectfully submit that, even if combinable, the cited references fail to disclose or suggest every element of the presently pending claims. Furthermore, there exists no reason why the skilled artisan would combine the cited references to arrive at the present claims.

Independent Claims 1, 13 and 20 recite, in part, a composition comprising whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan. Similarly, independent Claim 10 recites, in part, a method of producing an infant formula, the method comprising blending whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, and casein protein together with free arginine; free histidine; a milk protein comprising 5% or more of tryptophan and homogenising the blended mixture. In contrast, there exists no reason why the skilled artisan would combine the cited references to obtain the present claims, and even if combinable, the cited references fail to teach or suggest a milk protein comprising 5% or more of tryptophan for at least the reasons set forth below.

1. Even if combinable, the cited references do not teach or suggest a milk protein comprising 5% or more of tryptophan

Appellants respectfully submit that, even if combinable, the cited references fail to disclose or suggest a milk protein comprising 5% or more of tryptophan as required, in part, by all of the independent Claims 1, 10, 13 and 20 and Claims 3-4, 6-9 and 14-19 that depend therefrom. The Patent Office asserts that *Yonekubo* discloses milk proteins having 5% or more of tryptophan and relies on *Georgi* merely for the disclosure of hydrolysed whey proteins that do not contain caseino-glyco-macropeptide. See, Non-Final Office Action, page 4, lines 4-5; page 10, lines 16-22; page 11, lines 1-7. However, *Yonekubo* is entirely directed to providing essential amino acids to infants with urea cycle anomalies or nutritional disorders. See, *Yonekubo*, page 2, lines 13-24. "[T]he amino acids used are generally in a free form, but it is

possible to use histidine in hydrochloride form." See, *Yonekubo*, page 3, lines 24-25. Nowhere does *Yonekubo* disclose or suggest that amino acids other than histidine may be used in anything but their free form. In fact, *Yonekubo* specifically discloses adding tryptophan in its free form to the other amino acids and proteins. See, *Yonekubo*, page 3, line 1 (disclosing L-tryptophan weight percentage); page 4, line 48 (disclosing the amount of L-tryptophan added to a preparation). Nowhere does *Yonekubo* disclose or suggest that its composition includes tryptophan as a component of a milk protein.

The Patent Office asserts that *Yonekubo* discloses milk proteins having 5% of more of tryptophan merely because *Yonekubo* teaches a composition comprising natural milk proteins, whey powder, nutrients and carbohydrates. See, Non-Final Office Action, page 10, lines 21-22; page 11, lines 1-2. However, not all natural milk proteins are rich in tryptophan. For example, beta-lactoglobulin contains only 2 % of tryptophan. See, International Patent Application No. WO/2008/052995 to De Roos et al. ("*De Roos*"), page 2, lines 8-10. As such, *Yonekubo* does not disclose a milk protein comprising 5% or more of tryptophan merely because it teaches a composition comprising natural milk proteins.

The Patent Office also asserts that casein is a tryptophan-rich milk protein that contains greater than 5% of tryptophan. See, Non-Final Office Action, page 4, lines 4-5. However, contrary to the Patent Office's assertion, casein does not contain greater than 5% of tryptophan and instead contains approximately 1% of tryptophan. See, http://www.casein.com/products.htm; http://en.wikipedia.org/wiki/Tryptophan (stating that 600 g of casein yields approximately 4-8 g of tryptophan); and http://sci-toys.com/ingredients/casein.html. Likewise, sodium caseinate contains merely 1.1% of tryptophan. See, http://www.americancasein.com/pdfs/Sodium%20Caseinate-M%20.pdf. Therefore, one of ordinary skill in the art would understand that casein is not a milk protein that contains greater than 5% of tryptophan.

The Patent Office further asserts that the whey powder of *Yonekubo* is a milk protein that comprises 5% or more of tryptophan. See, Non-Final Office Action, page 11, lines 2-7. In support of its assertion, the Patent Office states that the whey powder of *Yonekubo* is a milk protein serum protein and notes that the major serum whey proteins are beta-lactoglobulin and alpha-lactalbumin, which has a high tryptophan content. See, Non-Final Office Action, page 11, lines 3-5. The Patent Office is correct that alpha-lactalbumin has a high tryptophan content of

approximately 5%. See, http://daviscofoods.com/fractions/alpha-beta.cfm; http://www.vital-news.com/docs/vital2.rtf. However, beta-lactoglobulin has a much lower tryptophan content of approximately 2%. See, *De Roos*, page 2, lines 8-10. Furthermore, beta-lactoglobulin comprises a much larger portion of whey protein (65%) as compared to alpha-lactalbumin (25%). See, http://en.wikipedia.org/wiki/Whey_protein. Therefore, the large amount of beta-lactoglobulin results in a low overall tryptophan content in the whey protein of approximately 2.7%. See, http://daviscofoods.com/fractions/alpha-beta.cfm. Thus, *Yonekubo* fails to disclose a milk protein comprising 5% or more of tryptophan as required, in part, by the present claims. Furthermore, nowhere does *Georgi* disclose or suggest a milk protein comprising 5% or more of tryptophan, nor does the Patent Office cite support for such claimed element. Therefore, the cited references fail to disclose or suggest a milk protein comprising 5% or more of tryptophan in accordance with the present claims.

2. There exists no reason why the skilled artisan would combine *Yonekubo* and *Georgi* to arrive at the present claims

Appellants submit that the cited combination would render *Yonekubo* unsatisfactory for its intended purpose. The Patent Office asserts that it would have been obvious to combine the hydrolysed sweet whey protein, in which caseino-glyco-macropeptide has been removed, of *Georgi* with the composition of *Yonekubo*. See, Non-Final Office Action, page 6, lines 7-11. However, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is not only no suggestion or motivation to make the proposed modifications, but the references also teach away from each other.

Yonekubo is entirely directed to providing essential amino acids to infants with urea cycle anomalies or nutritional disorders that do not receive a sufficient intake of essential amino acids. See, *Yonekubo*, page 2, lines 13-24. Because compositions consisting of only amino acids are unsuitable for administering to infants, *Yonekubo* combines natural proteins with the amino acids merely to make the composition more palatable. See, *Yonekubo*, page 3, lines 5-10. *Yonekubo* specifically includes threonine as one of the essential amino acids of its composition. See, *Yonekubo*, page 3, line 1 (disclosing L-threonine weight percentage); page 4, line 47 (disclosing the amount of L-threonine added to a preparation). In contrast, *Georgi* is directed to a milk baby

food containing a whey protein whose glyco-macropeptide content has been partially or completely removed in order to reduce the threonine content of the milk baby food. See, *Georgi*, Abstract; column 1, lines 66-67; column 2, lines 1-3. The entire purpose of *Georgi* is to provide a milk baby food or formula with a reduced threonine content. See, *Georgi*, column 1, lines 42-44. As such, Appellants respectfully submit that one of skill in the art would not combine the hydrolysed sweet whey protein of *Georgi* with the composition of *Yonekubo*.

The Patent Office asserts that one of ordinary skill in the art would be motivated to modify the compositions of *Yonekubo* because *Georgi* teaches that providing a formula with reduced threonine levels is beneficial to infants. See, Final Office Action, page 5, lines 1-6. However, although reduced threonine levels may be beneficial generally to infants, the compositions of *Yonekubo* are entirely directed to providing essential amino acids such as threonine to infants with an insufficient intake of such amino acids. See, *Yonekubo*, page 2, lines 13-24. Threonine provides some beneficial effects such as "promot[ing] normal growth by helping to maintain the proper protein balance in the body [and] support[ing] cardiovascular, liver, central nervous, and immune system function." See, http://www.vitaminstuff.com/amino-acid-threonine.html. Therefore, some threonine is advantageous to infants. Although reduced threonine levels may be beneficial to infants who are otherwise receiving a sufficient intake of threonine in their diet, *Yonekubo* specifically teaches providing threonine to infants who suffer disorders that create an insufficient intake of amino acids. See, *Yonekubo*, page 2, lines 13-24. Thus, Appellants respectfully submit that combining the reduced-threonine hydrolysed sweet whey protein of *Georgi* into the composition of *Yonekubo* would render *Yonekubo* unsatisfactory for its intended purpose of providing essential amino acids such as threonine to an infant with urea cycle anomalies or nutritional disorders that does not otherwise receive a sufficient intake of amino acids.

Furthermore, Appellants respectfully submit that *Yonekubo* teaches away from whey proteins that contain reduced levels of threonine. *Georgi* is entirely directed to a reduced-threonine milk baby food or formula. See, *Georgi*, column 1, lines 42-44. *Georgi* specifically teaches that conventional bovine whey protein foods are undesirable due to their high threonine content in comparison to human milk. See, *Georgi*, column 1, lines 18-24. *Georgi* expressly recognizes the need to reduce the threonine content of formulas. See, *Georgi*, column 1, lines 28-31. As such, *Georgi* is entirely directed to removing glyco-macropeptide from sweet whey in

order to reduce the threonine content of a formula. See, *Georgi*, column 1, lines 61-67; column 2, lines 1-3. Because *Georgi* is entirely directed to reducing the threonine content as much as possible to approximate that of human breast milk, the composition of *Georgi* does not include additional threonine.

In contrast, *Yonekubo* is entirely directed to providing essential amino acids such as threonine to infants with urea cycle anomalies or nutritional disorders that do not receive a sufficient intake of such amino acids. See, *Yonekubo*, page 2, lines 13-24. In fact, even though the whey protein of *Yonekubo* contains more threonine than the whey protein of *Georgi* because its glyco-macropeptide has not been removed, *Yonekubo* expressly discloses the use of additional threonine in its composition. See, *Yonekubo*, page 4, line 47. *Yonekubo* is completely unconcerned with reducing the levels of threonine to approximate those of breast milk and merely includes whey proteins to make its amino acid composition more palatable. See, *Yonekubo*, page 3, lines 5-10. Instead, *Yonekubo* is directed to providing amino acids such as threonine to infants that do not receive a sufficient intake of such amino acids. See, *Yonekubo*, page 2, lines 13-24. Thus, *Yonekubo* teaches away from a whey protein that contains reduced levels of threonine such as that of *Georgi*.

The Patent Office asserts that *Yonekubo* does not discount the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed because the need for reduced threonine levels does not equate to compositions with no threonine content. See, Final Office Action, page 5, lines 19-22. However, as discussed previously, the mere disclosure in *Yonekubo* of combining additional threonine with its whey protein that already has a high threonine content teaches away from whey proteins that contain reduced levels of threonine. If *Yonekubo* were not directed to providing a high level of threonine, it would not disclose the use of additional threonine when its whey protein already contains a high threonine content. In support of its assertion, the Patent Office argues that the addition of threonine in *Yonekubo* would not negate the effects of reduced threonine whey protein because "infant formula and breast milk clearly contain[] threonine." See, Final Office Action, page 6, lines 6-8. However, the Patent Office ignores the fact that the whey protein of *Yonekubo* already contains a high level of threonine because its glyco-macropeptide has not been removed. For example, *Georgi* specifically teaches that the amount of threonine in bovine whey proteins which contain glyco-macropeptide is significantly higher than that of human breast milk. See, *Georgi*, column 1,

lines 18-31 and 51-65. Furthermore, the Patent Office admits that *Yonekubo* does not disclose a whey protein from which caseino-glyco-macropeptide has been removed. See, Final Office Action, page 3, lines 18-20. Therefore, the whey protein of *Yonekubo* already has a threonine content higher than that of human breast milk. The entire purpose of reducing the level of threonine is to more closely approximate that of human breast milk. See, *Georgi*, column 1, lines 27-31. Thus, by expressly disclosing the addition of more threonine to its whey protein which already contains more threonine than human breast milk, *Yonekubo* would negate the effects of reduced threonine whey protein as taught by *Georgi*.

The Patent Office further asserts that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure. See, Final Office Action, page 6, lines 9-11. Although this assertion is true, Appellants respectfully submit that *Yonekubo* does not teach away from the whey protein of *Georgi* merely because its examples disclose the addition of threonine. As discussed previously, *Yonekubo* is concerned with providing essential amino acids such as threonine to infants who suffer from certain disorders and thus receive an insufficient intake of such amino acids. See, *Yonekubo*, page 2, lines 13-24. Therefore, *Yonekubo* discloses a composition containing whey protein which has a high level of threonine and additional threonine which is added to the whey protein. See, *Yonekubo*, page 3, line 1 (disclosing L-threonine weight percentage); page 4, line 47 (disclosing the amount of L-threonine added to a preparation). Because *Yonekubo* is entirely directed to providing a sufficient amount of amino acids such as threonine to compensate for a lack of amino acids resulting from certain disorders, *Yonekubo* teaches away from the reduced-threonine whey proteins of *Georgi*.

In sum, the Patent Office has failed to consider the cited references as a whole including those portions teaching against or away from each other and/or the claimed invention. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443, 448-49 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the [Appellant]." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009, (Fed. Cir. 1998). Because *Yonekubo* teaches away from *Georgi*, and the proposed combination would render

Yonekubo unsatisfactory for its intended purpose, one of ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

For the reasons discussed above, Appellants respectfully submit that Claims 1, 3-4, 6-10 and 13-20 are novel, nonobvious and distinguishable from the cited references.

Accordingly, Appellants respectfully request that the rejection of Claims 1, 3-4, 6-10 and 13-20 under 35 U.S.C. §103(a) be withdrawn. .

VIII. CONCLUSION

Appellants respectfully submit that the Patent Office has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 with respect to the rejection of Claims 1, 3-4, 6-10 and 13-20. Accordingly, Appellants respectfully submit that the obviousness rejection is erroneous in law and in fact and should therefore be reversed by this Board.

The Director is authorized to charge $540 for the Appeal Brief and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-780 on the account statement.

Respectfully submitted,

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Dated: December 5, 2008

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/088,766

1. A composition for an infant formula comprising: whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan.

3. The composition according to claim 1 which comprises 1.5% to 3% by weight of arginine; tryptophan and histidine.

4. The composition according to claim 1 which comprises a lipid source, a carbohydrate source, and a protein source.

6. The composition according to claim 1 wherein the whey protein is treated to remove lactose.

7. The composition according to claim 1 which comprises 6% to 50% by weight of whey protein and 20% to 40% casein protein.

8. The composition according to claim 1 which comprises 0% to 0.1% by weight histidine, 0.1% to about 0.3% by weight arginine, and 0.3 to 0.5% by weight tryptophan.

9. The composition according to claim 1 which comprises 0.2% to 0.4% by weight histidine, 1% to 2% by weight arginine, and 0.2% to 0.4% by weight tryptophan.

10. A method of producing an infant formula, the method comprising blending whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, and casein protein together with free arginine; free histidine; a milk protein comprising 5% or more of tryptophan and homogenising the blended mixture.

13. An infant formula comprising: hydrolysed sweet whey protein, from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more tryptophan.

14. The infant formula of claim 13 comprising from 9.0 to 10.0 w/w% of all protein sources contained in the infant formula.

15. The infant formula of claim 13 comprising 1.5% to 3% by weight of arginine; tryptophan and histidine.

16. The infant formula of claim 13 comprising a lipid source, a carbohydrate source, and a protein source.

17. The infant formula of claim 13 comprising 6% to 50% by weight of whey protein and 20% to 40% casein protein.

18. The infant formula of claim 13 comprising 0.1% to 0.3% by weight arginine, and 0.3 to 0.5% by weight tryptophan.

19. The infant formula of claim 13 comprising 0.2% to 0.4% by weight histidine, 1% to 2% by weight arginine, and 0.2% to 0.4% by weight tryptophan.

20. A method of providing nutrition to an infant, the method comprising administering to the infant a composition comprising whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan.

EVIDENCE APPENDIX

EXHIBIT A: Non-Final Office Action dated January 16, 2008

EXHIBIT B: Final Office Action dated July 14, 2008

EXHIBIT C: Japanese Patent Publication No. 58-165742 A1 to Yonekubo et al. ("*Yonekubo*"), cited by the Patent Office in the Non-Final Office Action dated January 16, 2008 and the Final Office Action dated July 14, 2008

EXHIBIT D: U.S. Patent No. 5,916,621 to Georgi et al. ("*Georgi*"), cited by the Patent Office as the English language version of International Patent Application No. WO 95/17102 in the Non-Final Office Action dated January 16, 2008 and the Final Office Action dated July 14, 2008

RELATED PROCEEDINGS APPENDIX

None.

EXHIBIT A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,766	06/20/2002	Martinas Kuslys	112843-043	2286

29157 7590 01/16/2008

BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
01/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/088,766	KUSLYS ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-10 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-10 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2007 has been entered.

Amendment Entry

2. The amendment filed October 23, 2007 has been entered. Claim 14 has been amended. Claims 2, 5, and 11-12 have been cancelled. Claims 1, 3, 4, 6-10 and 13-20 are under consideration in this office action.

Withdrawal of Rejections

3. The rejection of claim 14 under 35 U.S.C. 112, second paragraph has been withdrawn in view of applicants' amendments.

Response to Arguments

4. Applicant's arguments filed October 23, 2007 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-4, 6-10 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yonekubo et al., (JP-002158742) in view of Georgi et al., WO 95/17102. WO 95/17102 provides priority to US Patent 5,916, 621; however US Patent 5,916,621 will reference the English language version of WO 95/17102.

Claim 1 is drawn to a composition for an infant formula comprising: whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan. Claim 10 is drawn to method of producing an infant formula, the method comprising the step of blending whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, and casein protein together with free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan, and homogenizing the blended mixture. Claim 20 is drawn to a method of providing nutrition to an infant, the method comprising administering to the infant a composition comprising whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more tryptophan.

Yonekubo et al., teach highly digestible nutritive compositions for infant use (page 2). Yonekubo et al., teach the nutritive composition comprises natural milk proteins, amino acids as the protein source and nutrients such as lipids (fats) and carbohydrates (page 2, lines 8-11). Yonekubo et al., teach casein, a tryptophan rich milk protein is at 24-32% by weight which has at level of 5% or more of tryptophan (page 2, lines 32-33). Yonekubo et al., teach the whey protein is at 30-40% by weight while the casein protein is at 24-32% by weight (page 2). Yonekubo et al., teach the whey powder obtained from the milk serum portion that is left after casein has been removed (page 3, lines 20-21). Therefore casein is removed from the whey to produce sweet whey. Yonekubo et al., teach the whey powder is further treated and lactose is eliminated from it, thereby resulting in a product useable in a nutritive infant composition (page 3, lines 21-22). Yonekubo et al., teach the composition uses highly desirable natural proteins and adds essential amino acids to fortify the proteins, thereby reducing the overall protein content (page 3, lines 2-7). Yonekubo et al., teach the amino acids used in the compositions are free amino acids (page 3, lines 24-25). The composition comprises histidine at 1.4 to 2.0% by weight and has tryptophan is at 0.5-0.7% by weight (page 3). It is noted that Yonekubo et al., teach different concentrations for the arginine and tryptophan, however limitations such as different concentrations are viewed as limitations not imparting patentability. There is no evidence that these limitations provide unexpected results. The composition reduces the levels of protein ingested, provides natural proteins that are beneficial in terms of digestive absorption, succeeds in reducing total protein levels while providing supplementary essential amino acids (page 3, lines 2-5).

Yonekubo et al., teach a method of making the infant formulas, see Working Example 1. Yonekubo et al., teach the nutritive composition can be easily digested and utilized by babies and infants (page 2, lines 5-7). Yonekubo et al., teach in order to provide optimal emulsification and homogenization, the addition of surface active agents is necessary (page 3, lines 38-40). Yonekubo et al., teach the components are homogeneously mixed and formulated into a powder thereby yielding an infant use nutritive composition (page 4, lines 18-22). Yonekubo et al., teach the composition is administered by dissolution in water and then administering it to an infant (page 5, lines 3-5). However Yonekubo et al., do not teach the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed.

Georgi et al, teach that it is important to use whey powder/proteins that do not contain glycomacropeptide (GMP) because GMP causes the very high threonine content (col. 1-2, lines 65-2). It is noted that high threonine levels in infants causes hyperthreoninemia. Georgi et al., teach the production of milk baby foods, which have whey protein as the dominant product in such foods (col.1, lines 18-21). Georgi et al, teach milk baby foods have the disadvantage of having a high threonine content that causes high levels of threonine in the plasma of infants (col. 1, lines 20-25). Georgi et al., found that threonine content in whey powders are higher due to the addition of whey proteins (col.1, lines 37-41). Therefore Georgi et al., teach the need for whey protein dominant milk baby food or formula with a reduced threonine content (col.1, lines 42-45). Georgi et al, teach whey powder or whey proteins used in the production of milk baby foods are obtained exclusively from sweet whey which is produced by the

precipitation and removal of caseins (col. 1, lines 51-55). Georgi et al, teach GMP must be completely removed by suitable processes; and removal processes are commercially well known (col.2, lines 5-14). Georgi et al, teach the sweet whey after the removal GMP is further hydrolysed with enzymes according to known processes (col. 2, lines 50-52). Therefore Georgi et al, teach the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed.

Therefore it would have been prima facie obvious at the time of applicants' invention to modify the sweet whey composition for an infant formula, along with the method of production and method of providing an infant formula as taught by Yonekubo et al., wherein the modification incorporates the use of hydrolysed sweet whey protein from which casein-glyco-macropeptide has been removed as taught by Georgi et al. One of ordinary skill in the art would be motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach that providing formula without high threonine levels is advantageous to infants and that by removing the GMP from whey, one of ordinary skill in the art can provide formula with significantly reduced the threonine levels which is beneficial to infants. No more than routine would have been required to modify the composition and method of Yonekubo et al., by incorporating the hydrolysed sweet whey when Yonekubo et al., and Georgi et al., teach that the removal of casein-glyco-macropeptide and the hydrolysis of sweet whey are performed by used well known processes and desirable in infant formulations.

Moreover, one of ordinary skill in the art would have a reasonable expectation of success since well known commercially available methods were used to formulate the

infant formulas and method of production and administration which had been routinely observed in the prior art to provide baby formulas with reduced threonine content by adding GMP free whey proteins which are dominant in baby milk foods. Furthermore, the limitations drawn to the different concentrations for the arginine and tryptophan are viewed as merely optimizing the experimental parameters and not imparting patentability; thus no more than routine skill would have been required to change the concentration in the well known compositions and method of production as taught by Yonekubo et al., in view of Georgi et al.

Response to Arguments

6. Applicant's arguments have been fully considered but they are not persuasive. The rejection of claims 1, 3-4, 6-10 and 13-20 under 35 U.S.C. 103(a) as being unpatentable over Yonekubo et al., (JP-002158742) in view of Georgi et al., WO 95/17102. WO 95/17102 provides priority to US Patent 5,916, 621; however US Patent 5,916,621 will reference the English language version of WO 95/17102 is maintained.

Applicant argues that the Yonekubo et al., reference teaches away from the claimed invention because Yonekubo et al., teach an example where threonine is added to the composition. However, it is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*,

27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims, rather the references teach the need to reduce the threonine content.

Therefore, contrary to applicants' arguments, one of ordinary skill in the art would have been motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach that providing formula without high threonine levels achieved by removing the GMP from whey, is advantageous to infants.

The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it

would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Therefore applicant's argument is not persuasive especially when considering one of ordinary skill in the art knew that high threonine levels in infants causes hyperthreoninemia; and Georgi et al., teach milk baby foods have the disadvantage of having a high threonine content that causes high levels of threonine in the plasma of infants therefore Georgi et al., teach the need for milk baby food or formula with a reduced threonine content. Accordingly, applicants' arguments are not persuasive, since the instant claims do not become patentable simply because the prior art products have been described as somewhat inferior to other products for the same use.

Applicants argue that the references fail to disclose or suggest every element of the claims, in that the references do not the milk protein comprising 5% or more of tryptophan is not taught by Yonekubo et al.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, contrary to applicants arguments, it would have been prima facie obvious at the time of applicants' invention to modify the sweet whey composition for an infant formula, along with the method of production and method of providing an infant formula as taught by Yonekubo et al., wherein the modification merely incorporates the use of hydrolysed sweet whey protein from which casein-glyco-macropeptide has been removed as taught by Georgi et al., in order to advantageously remove the GMP from whey and provide formula without high threonine levels to infants. Moreover, no more than routine would have been required to modify the composition and method of Yonekubo et al., by incorporating the hydrolysed sweet whey when Yonekubo et al., and Georgi et al., teach that the removal of casein-glyco-macropeptide and the hydrolysis of sweet whey are performed by used well known processes and desirable in infant formulations.

Applicants' argue that the references do not teach a milk protein having 5% or more of tryptophan. Applicants' urge that Yonekubo teaches adding L-tryptophan as a separate or free ingredient in the composition and not as a sub-component of a milk protein. Applicants' argue that sodium caseinate does not contain 5% or more of tryptophan, however the issue is not the amount of tryptophan in sodium caseinate. Contrary to applicants' statements, Yonekubo et al., clearly teach the inclusion of a milk protein comprising 5% or more of tryptophan. Yonekubo et al., teach compositions

comprising natural milk proteins, whey powder, nutrients and carbohydrates. Thus Yonekubo et al., teach milk proteins having 5% or more of tryptophan. Yonekubo et al., teach whey powder as a milk protein serum protein. It is well known that the major serum whey proteins are beta-lactoglobulin and alpha-lactoalbumin which is a whey protein with a high tryptophan content. Therefore Yonekubo et al., teach a milk protein having 5% or more of tryptophan that does not include the amino acids added in free form. Applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
December 30, 2007

MARK NAVARRO
PRIMARY EXAMINER

Notice of References Cited	Application/Control No. 10/088,766	Applicant(s)/Patent Under Reexamination KUSLYS ET AL.	
	Examiner Ja-Na Hines	Art Unit 1645	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	WO 95/17102	06-1995	World	Georgi et al.	A23J 1/20
*	O	58-165742	09-1983		Yonekubo et al.	A23J 3/00
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,766	06/20/2002	Martinas Kuslys	112701-780	2286

29157 7590 07/14/2008
BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
07/14/2008	ELECTRONIC

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The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/088,766	KUSLYS ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

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- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-10 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-10 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

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Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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Attachment(s)

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2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Claims 2, 5, and 11-12 are cancelled. Claims 1, 3, 4, 6-10 and 13-20 are under consideration in this office action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 16, 2008 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The rejection of claims 1, 3-4, 6-10 and 13-20 under 35 U.S.C. 103(a) as being unpatentable over Yonekubo et al., (JP-002158742) in view of Georgi et al., WO 95/17102 is maintained.

It is noted that WO 95/17102 provides priority for US Patent 5,916, 621; however US Patent 5,916,621 will act as the English language version of WO 95/17102.

The claims are drawn to a composition for an infant formula comprising: whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-

glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan. Claim 10 is drawn to method of producing an infant formula, the method comprising the step of blending whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, and casein protein together with free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan, and homogenizing the blended mixture. Claim 20 is drawn to a method of providing nutrition to an infant, the method comprising administering to the infant a composition comprising whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more tryptophan.

The rejection is on the grounds that Yonekubo et al., teach highly digestible nutritive compositions for infant use comprising natural milk proteins, amino acids as the protein source, nutrients such as lipids (fats) and carbohydrates. Yonekubo et al., teach the whey powder obtained from the milk serum portion that is left after casein has been removed. Therefore casein is removed from the whey to produce sweet whey. Yonekubo et al., teach the amino acids used in the compositions are free amino acids such as histidine and tryptophan. However Yonekubo et al., do not teach the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed. Georgi et al, teach that it is important to use whey powder/proteins that do not contain glycomacropeptide (GMP).

Therefore it would have been prima facie obvious at the time of applicants' invention to modify the sweet whey composition for an infant formula, along with the method of production and method of providing an infant formula as taught by Yonekubo et al., wherein the modification incorporates the use of hydrolysed sweet whey protein from which casein-glyco-macropeptide has been removed as taught by Georgi et al. Moreover, one of ordinary skill in the art would have a reasonable expectation of success since well known commercially available methods were used to formulate the infant formulas and method of production and administration which had been routinely observed in the prior art to provide baby formulas by adding GMP free whey proteins which are dominant in baby milk foods.

Response to Arguments

4. Applicant's arguments have been fully considered but they are not persuasive. The rejection of claims 1, 3-4, 6-10 and 13-20 under 35 U.S.C. 103(a) as being unpatentable over Yonekubo et al., (JP-002158742) in view of Georgi et al., WO 95/17102 is maintained for reasons of record.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would be motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach that providing formula without high threonine levels is advantageous to infants and that by removing the GMP from whey, one of ordinary skill in the art can provide formula with significantly reduced the threonine levels which is beneficial to infants. Furthermore, no more than routine would have been required to modify the composition and method of Yonekubo et al., by incorporating the hydrolysed sweet whey when Yonekubo et al., and Georgi et al., teach that the removal of casein-glyco-macropeptide and the hydrolysis of sweet whey are performed by used well known processes and desirable in infant formulations.

Therefore applicants' arguments are not persuasive.

Again, applicants' argue that the Yonekubo et al., reference teaches away from the claimed invention because Yonekubo et al., teach an example where threonine is added to the composition. Contrary to applicants' arguments, one of ordinary skill in the art would have been motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach that providing formula without high threonine levels achieved by removing the GMP from whey, is advantageous to infants. It is noted that the need for reduced threonine levels does not equate to compositions not having any threonine content as Applicants argue. The teachings of Yonekubo et al., where threonine is added does not discount the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed.

The prior art teaches the need for reduced levels, which Yonekubo et al., in view of Georgi et al., teach. Furthermore, Quero et al., [Journal of Pediatric Gastroenterolgy and Nutrition. 1997. Vol. 24(4): 491], teach the incidence of hyperthreoninemia is reduced by feeding infants whey predominant formula without GMP. Quero et al., clearly states that threonine concentrations are still found in GMP-free formula and in breast milk. Therefore applicants' argument that the addition of threonine would negate the effects of reduced threonine when protein is not persuasive, since infant formula and breast milk clearly contains threonine.

It is also the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims, rather the references teach the need to reduce the threonine content, not eliminate the threonine content.

Therefore, contrary to applicants' arguments, one of ordinary skill in the art would have been motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach advantageously providing infant formula without high threonine levels is achieved by removing the GMP from whey.

The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Therefore a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Therefore applicant's argument is not persuasive especially when considering that one of ordinary skill in the art knew that high threonine levels in infants causes hyperthreoninemia; and Georgi et al., teach milk baby foods have the disadvantage of having a high threonine content therefore Georgi et al., teach the need for milk compositions with a reduced threonine content. Accordingly, applicants' arguments are not persuasive, since the instant claims do not become patentable simply because the prior art products have been described as somewhat inferior to other products for the same use.

Applicants' argue that the references fail to disclose or suggest every element of the claims, in that the references do not the milk protein comprising 5% or more of tryptophan is not taught by Yonekubo et al.

Applicants' argue that the references do not teach a milk protein having 5% or more of tryptophan. Contrary to applicants' statements, Yonekubo et al., clearly teach the inclusion of a milk protein comprising 5% or more of tryptophan. Yonekubo et al.,

teach compositions comprising natural milk proteins, whey powder, nutrients and carbohydrates. Furthermore, neither Applicants claims nor specification state what specific milk protein is comprised in the instantly claimed composition, which would allow for an appropriate comparison. Yonekubo et al., teach milk proteins having 5% or more of tryptophan. Yonekubo et al., teach whey powder as a milk protein serum protein and casein. Therefore Yonekubo et al., teach a milk protein having 5% or more of tryptophan that does not include the amino acids added in free form. Applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

5. No claims allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645

Notice of References Cited	Application/Control No. 10/088,766	Applicant(s)/Patent Under Reexamination KUSLYS ET AL.	
	Examiner JaNa Hines	Art Unit 1645	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	WO 95/17102	06-1995	World	Georgi et al.	A23J 1/20
*	O	58-165742	09-1983		Yonekubo et al.	A23J 3/00
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PTO/SB/08e (03-08)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	10088766
Filing Date	2002-06-20
First Named Inventor	Kuslys, et al.
Art Unit	1645
Examiner Name	J. Hines
Attorney Docket Number	112701-780

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/JH/	1	4485040		1984-11-27	Roger, et al.	
/JH/	2	5916621		1999-06-29	Georgi, et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
/JH/	1	0 418 593	EP		2008-04-15	Milupa AG (DE)		☒
/JH/	2	95/17102	WO		1995-06-29	Milupa AG (DE)		☒

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	10088766
	Filing Date	2002-06-20
	First Named Inventor	Kuslys, et al.
	Art Unit	1645
	Examiner Name	J. Hines
	Attorney Docket Number	112701-780

/JH/	3	0 421 309	EP		1991-04-10	Sandoz Nutrition Ltd.		☒
/JH/	4	0 880 092	EP		1998-12-02	Nestle Produkte AG		☒
/JH/	5	58-165742	JP		1983-09-30	Meiji Dairy Co. Ltd.		☒

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
/JH/	1	MARSHALL, Casein Macropeptide From Whey - A New Product Opportunity, Food Research Quarterly, Volume 51, Nos. 1 &2, (1991), p. 86-91.	☒
/JH/	2	TANIMOTO, ET AL., Large-scale Preparation of k-Casein Glycomacropeptide from Rennet Casein Whey, Biosci, Biotech, Biochem., 56 (1992), p. 140-141.	☒
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/JH/	5	WALSTRA ET AL., Diary Chemistry and Physics, John Wiley and Sons, 1984, New York, Chapter 1, p. 1-11.	☒
/JH/	6	Idem, Appendix, Table A.6, p. 402-403.	☒

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	10088766
Filing Date	2002-06-20
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Art Unit	1645
Examiner Name	J. Hines
Attorney Docket Number	112701-780

/JH/	7	Idem, Appendix, Table A.15, p. 416-422.	☒
	8	IMBERT-BONDAVEN, 1977, Etude de l'evolution de la composition des lactoserums au cours de leur conservation. Le Lait 568, p. 521-546.	☒
/JH/	9	ALAIS ET AL., 1975, Milk proteins: Biochemical and biological aspects, World review of Nutrition and Dietetics, 20: p. 66-167.	☒
/JH/	10	SOUCI FACHMAN KRAUT, Food Composition and Nutrition Tables, Medpharm Scientific Publishers Stuttgart, Boca Raton, 1994, p. 41-46.	☒
/JH/	11	USDA Agricultural Research Data. The National Nutrient Database for standard reference. Release 18. Whey, acid, dried. http://www.nal.usda.gov/fnic/foodcomp/egi-bin/list_nut_edit.pl.	☒
/JH/	12	International Preliminary Examination Report for PCT/EP00/08910	☒
/JH/	13	QUERO, ET AL., 1997 Reduction of hyperthreonemia in term infants fed a whey predominant formula without glycomacropeptide, Journal of Pediatric Gastroentrology Nutrition, Volume 24, p. 491.	☒
/JH/	14	Opposition on behalf of Friesland Brands B.V. to EP 1 220 620 Composition comprising casein protein and whey protein in the name of Societe des Produits Nestle S.A.	☒
/JH/	15	Opposition on behalf of Numico Research B.V. to EP 1 220 620 Composition comprising casein protein and whey protein in the name of Societe des Produits Nestle S.A.	☒

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EXAMINER SIGNATURE

Examiner Signature	/Jana Hines/ (07/07/2008)	Date Considered	07/07/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	10088766
Filing Date	2002-08-20
First Named Inventor	Kuslys, et al.
Art Unit	1645
Examiner Name	J. Hines
Attorney Docket Number	112701-780

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

EXHIBIT C

(19) Japan Patent Office
(12) Public Patent Bulletin (A)

(11) Public Patent Bulletin Number 1983-165742

(43) 30th September 1983

(51) Int. Cl[3]	Identification number	JPO File number
A23J 3/00		7915-4B
	Request for examination	Number of inventions 1 Not Submitted

(3 pages)

(54) Nutritive Composition for Infant

(21) Patent Application 1982-46275
(22) Filed 25th March 1982

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Specification

1. Title of the Invention

Nutritive Composition for Infant

2. What is claimed is:

The present invention is a nutritive composition for infant, characterized in that its weight is based on proteins, being total nitrogenous compounds, the nitrogenous compounds it contains being a source of protein in the following composition, and in which there is a lowered component ratio of protein.

Casein and casein salts (casein protein)
24-32 (% of weight)
Whey powder (whey protein)

	30-40
L-isoleucine	2.2-3.0
L-leucine	8.5-11.3
L-methionine	0.3-0.4
L-cystine	2.4-3.2
L-phenylalanine	2.7-3.7
L-tyrosine	2.7-3.7
L-threonine	3.0-4.0
L-tryptophan	0.5-0.7
L-valine	4.0-5.4
L-arginine	3.9-5.3
L-histidine	1.4-2.0

3. Detailed description of the invention

The present invention is a nutritive composition for infant that is highly superior in terms of digestive absorption.

In greater detail, the present invention is a nutritive composition for infants as a source of protein, comprising natural milk proteins and amino acids and containing fats, carbohydrates, minerals, vitamins and other nutrients.

One of the aims of the present invention is to provide a nutritive composition that contains an optimal source of protein in the form of a therapeutic feed for infant patients suffering from urea cycle anomalies that occur in the liver. A further aim of the present invention is to provide a nutritive composition for infants with nutritional disorders.

In general, when infants suffer from urea cycle anomalies, ammonia levels in the blood and cerebro-spinal fluid become raised, and a low protein diet is necessary in order to lower these ammonia levels, this means that the infant then requires a sufficient intake of essential amino acids. Furthermore, proteolysis and digestive capabilities in infants with nutritional disorders may be lowered due to an insufficient intake of essential amino acids.

The present invention is a nutritive composition for infant, characterized in that its weight basis is on proteins, being nitrogenous compounds, the nitrogenous compounds it contains being a source of protein in the following composition, and in which there is a lowered component ratio of protein, as a nutritive composition for treating the aforementioned types of nutritional disorders in infants.

Casein and casein salts (casein protein)	
	24-32 (% of weight)
Whey powder (whey protein)	
	30-40
L-isoleucine	2.2-3.0
L-leucine	8.5-11.3
L-methionine	0.3-0.4
L-cystine	2.4-3.2

L-phenylalanine	2.7-3.7
L-tyrosine	2.7-3.7
L-threonine	3.0-4.0
L-tryptophan	0.5-0.7
L-valine	4.0-5.4
L-arginine	3.9-5.3
L-histidine	1.4-2.0

The present invention does not just reduce the levels of protein ingested, in addition to providing natural proteins that are beneficial in terms of digestive absorption; it also succeeds in reducing total protein levels whilst providing supplementary essential amino acids. Preparations consisting of only amino acids have an unpleasant smell and a bitter taste, making them hard to administer, and in solution they have a high osmotic pressure which makes them unsuitable for administering to infants.

The present invention, a nutritive composition, combines natural proteins and amino acids making it very easy for infants to take; it can be made more palatable with the addition of a small amount of honey which makes it easier to administer.

Moreover, the present invention, a nutritive composition, can be administered orally, or by enteral intubation.

The casein used in the present invention is generally in the form of salts but in order to dissolve the casein, sodium salts, potassium salts and calcium salts can be used to obtain good dispersibility and solubility.

Whey powder is obtained from the whey portion of cow's milk once the casein has been removed from it. It may be used in a further demineralised state or with lactose removed.

In addition, the amino acids used are generally in a free form, but it is possible to use histidine in hydrochloride form.

The basic composition of the present invention, a nutritive composition for infant, comprises casein, whey powder, and the necessary formulation of amino acids, but in addition, carbohydrates, fats, minerals, vitamins and other ingredients may be added where appropriate. For carbohydrates, it can be used combined with lactose and a starch decomposition product, honey or other energy source, with their usage weight being 40-60% of weight.

For fats, sunflower oil, palm oil, corn oil, soybean oil, coconut oil and other vegetable oils, lard and other animal fats and equivalent MCT fats (medium-chain triglyceride) can be used. The usage amount for these is 20-50% of weight.

In addition, in order to emulsify the amino acids and the fat chains, sugar esters, monoacylglycerol, lecithin and other surfactants are added in order to provide optimal emulsification and homogenisation at the time when the composition is used.

For vitamins, in order to satisfy the "Recommended International Standards for Foods for Infants and Children" CAC/RS72-1976 of the Codex Alimentarius Commission of

the Joint FAO/WHO Food Standards Programme (hereafter referred to as "recommended standards"), vitamins A, B_1, B_6, B_{12}, C, D, E, K_1, pantothenic acid, niacin, folacin, biotin, inositol, choline (may also be substituted with lecithin) and others may be used. For all vitamin types a usage amount of 0.1% of the weight is sufficient.

For minerals, in order to satisfy the recommended standards, ferrous sulphates, sodium ferrous citrate and other iron salts, copper gluconate and other copper salts, zinc sulphate, zinc chloride and other zinc salts, manganese acetate and other manganese salts, cobalt acetate and other cobalt salts, potassium iodide, potassium carbonate and other potassium salts and iodides, magnesium chloride and other magnesium salts, trisodium citrate, sodium chloride and other sodium salts, calcium glycerophosphate, calcium carbonate, calcium chloride and other calcium salts and chlorides, potassium dihydrogen phosphate, dipotassium hydrogen phosphate and other phosphates and potassium salts can be used. For all minerals the usage amount is 2-3% of weight.

Each of the above ingredients are mixed together uniformly in a powder preparation to make up the nutritive composition for infant.

The present invention, a nutritive composition for infant, is a powder preparation, the standard dose of which is a concentration of 15%W/V dissolved in water and administered. The dose can either be administered orally, or by enteral intubation.

The present invention, a nutritive composition for infant, can lower ammonia concentrations in the blood and cerebro-spinal fluid of infants through administration to patients with urea cycle anomalies and can also be used as a feed.

In addition, the present invention, a nutritive composition for infant, can be administered to infants that are undernourished, in order to provide a well-balanced intake of essential amino acids even in severe cases, where proteins are restricted, for example due to renal insufficiency, with the use of only a small amount of protein. Following is a practical example of the present invention

Practical Example 1.

The following ingredients mixed together uniformly in a preparation.

Sodium caseinate	2.243g
Whey powder	3.031g
L-isoleucine	0.157g
L-leucine	0.582g
L-methionine	0.016g
L-cystine	0.165g
L-phenylalanine	0.189g
L-tyrosine	0.207g
L-threonine	0.230g
L-tryptophan	0.037g
L-valine	0.275g
L-arginine	0.276g

L-histidine hydrochloride	0.136g
MCT fat	16.660g
Plant oil	27.568g
Lactose	53.54g
Honey	3.270g
Niacinamide	6.0mg
Vitamin B_2	0.91mg
Vitamin B_{12}	7.9 μg
Inositol	12.49mg
Biotin	0.06mg
DL-a-Tocopherol	6.0mg
Vitamin A and Vitamin D compound	6.711mg
Vitamin K_1	114 μg
Thiamine hydrochloride (V. B_1)	0.72mg
Pyridoxine hydrochloride (V. B_6)	0.43mg
Ascorbic acid (V. C)	54.0mg
Folacin	0.24mg
Calcium pantothenate	2.40mg
Sodium ferrous citrate	80.0mg
Potassium iodide	0.11mg
Calcium glycerophospate	427.3mg
Calcium carbonate	565.58mg
Calcium hydroxide	41.4mg
Calcium chloride dihydrate	33.0mg
Potassium dihydrogen phosphate	108.3mg
Dipotassium hydrogen phosphate	231.3mg
Hexahydrate magnesium oxide	294.0mg
Sodium chloride	207.9mg
Trisodium citrate dihydrate	44.1mg
Lecithin powder	90.0mg
Sugar ester	225.0mg
Monoacylglycerol	114.0mg
Copper sulphate pentahydrate	1.552mg
Zinc chloride	51.3mg
Manganese acetate tetrahydrate	0.669mg
Cobalt acetate tetrahydrate	0.211mg

This nutritive composition for infant is dissolved 15% W/V in water at 40°C, and the dose administered to the infant either orally or enterally.

Agent: Chikao Toda, Patent Attorney

⑲ 日本国特許庁 (JP)　　⑪ 特許出願公開
⑫ 公開特許公報 (A)　　昭58—165742

⑤Int. Cl.³　識別記号　庁内整理番号　⑬公開 昭和58年(1983)9月30日
A 23 J 3/00　7915—4B

発明の数 1
審査請求 未請求

(全 3 頁)

④乳幼児用栄養組成物

②特　願 昭57—46275
②出　願 昭57(1982)3月25日
⑦発 明 者 米久保明得
国分寺市本多3の7の6
⑦発 明 者 山本良郎
東村山市本町2の14の12
⑦発 明 者 土屋文安
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⑦出 願 人 明治乳業株式会社
東京都中央区京橋2丁目3番6号
⑦代 理 人 弁理士 戸田親男

明　細　書

1.発明の名称

乳幼児用栄養組成物

2.特許請求の範囲

蛋白源としての全窒素化合物重量基準で、下記組成から成る窒素化合物を蛋白源として含有し、蛋白食の含有比を低下させたことを特徴とする乳幼児用栄養組成物。

カゼイン又はその塩(カゼイン蛋白として)
24～32(重量%)

ホエーパウダー(乳清蛋白として)
30～40

L-イソロイシン	2.2～3.0
L-ロイシン	8.5～11.5
L-メチオニン	0.3～0.4
L-シスチン	2.4～3.2
L-フエニルアラニン	2.7～3.7
L-チロシン	2.7～3.7
L-スレオニン	3.0～4.0
L-トリプトファン	0.5～0.7
L-バリン	4.0～5.4
L-アルギニン	3.9～5.3
L-ヒスチジン	1.4～2.0

3.発明の詳細な説明

本発明は、消化吸収のきわめてすぐれた乳幼児用栄養組成物に関するものである。

更に詳細には、本発明は、自然の牛乳蛋白とアミノ酸を蛋白源とし、脂肪、炭水化物、ミネラル、ビタミン等の栄養素を含有した乳幼児用栄養組成物に関するものである。

本発明の目的の一つは、肝臓における尿素サイクル異常を起こした乳幼児患者の治療栄養補給食として最適な蛋白源を含有する栄養組成物を提供することにある。本発明の他の目的は、栄養障害を起こした乳幼児用栄養組成物を提供することにある。

一般に、乳幼児が尿素サイクル異常を起こした時には血中、髄液中のアンモニア値が高くなるのであるが、このアンモニア値を低下させるには低蛋白食が必要になると同時に必須アミノ酸は十分

摂取させなければならない状態となる。また、乳幼児が栄養障害を起こすと蛋白分解能および吸収、利用性が低下するために必須アミノ酸の摂取が不十分な状態となるのである。

本発明は、このような乳幼児の機能障害に対処するための栄養組成物に関するもので、蛋白源としての全窒素化合物重量基準で、下記組成から成る窒素化合物を蛋白源として含有し、蛋白量の含有比を低下させたことを特徴とする乳幼児用栄養組成物である。

カゼイン又はその塩（カゼイン蛋白として）
24～32（重量%）
ホエーパウダー（乳清蛋白として）
30～40
L－イソロイシン 2.2～3.0
L－ロイシン 8.5～11.3
L－メチオニン 0.3～0.4
L－シスチン 2.4～3.2
L－フェニルアラニン 2.7～3.7
L－チロシン 2.7～3.7

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用いられるが、カゼインを溶解するための塩としては、ナトリウム塩、カリウム塩、カルシウム塩等分散性、溶解性を良くする各種の塩を使用することができる。

ホエーパウダーとしては牛乳からカゼインを除去した後の乳清部分から得ることができる。また更に脱塩したもの、あるいは乳糖を除いたものなどの使用が可能である。

また、アミノ酸類は一般に遊離形で使用されるが、ヒスチジンは塩酸塩でも使用できる。

本発明の乳幼児用栄養組成物は、カゼイン、ホエーパウダー、アミノ酸の必須組成を基本的成分とするものであるが、その他にも炭水化物、脂肪、ミネラル、ビタミンなどが適宜添加されるものである。炭水化物としては乳糖と澱粉分解物、ハチミツ等のエネルギー源となるものを組み合わせて使用され、その使用量は40～60重量%である。

脂肪としては、例えばサフラワー油、パーム油、コーン油、大豆油、ヤシ油等の植物性油、ラード等の動物性油並びにMCT油（Midium－Chain－

L－スレオニン 3.0～4.0
L－トリプトファン 0.5～0.7
L－バリン 4.0～5.4
L－アルギニン 3.9～5.5
L－ヒスチジン 1.4～2.0

本発明においては、単に蛋白摂取量を減少させるのではなく、消化吸収の良い自然蛋白とそれに加え、さらに必要なアミノ酸を補強した形で全体の蛋白量を低下させることに成功したものである。アミノ酸のみで調製したものは、アミノ酸特有の臭気苦味があり、飲みにくく、また溶解時の浸透圧も高く乳幼児にとつて好ましいものではない。

本発明の栄養組成物は自然蛋白とアミノ酸を組み合わせることによりきわめて飲みやすくなつており、更にこれとヘチミツを少量添加することによつて一層味がよくなり、飲みやすくすることも可能である。

また、本発明の栄養組成物は、経口投与および経管等の経腸的投与が可能である。

本発明に使用するカゼインは、一般に塩の型で

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Triglyceride）等が使用される。その使用量は20～50重量%である。

また、アミノ酸と脂肪の系を乳化させる為にシュガーエステル、モノグリセリド、レシチン等の界面活性剤を添加しておいて、使用時乳化、均質化が容易となるようにしておくのがよい。

ビタミンとしては、FAO／WHO合同食品規格計画Codex 食品規格委員会CAC／RS72－1976乳児用調製乳の動告国際規格（以下動告規格という）を満たせるように、ビタミンA，B1，B2，B6，B12，C，D，E，K1，パントテン酸，ナイアシン，葉酸，ビオチン，イノシット，コリン（レシチンで代用することもできる）等が使用される。ビタミン類全体の使用量は0.1重量%程度で十分である。

ミネラルとしては、動告規格を満たせるように、硫酸第一鉄，コハク酸クエン酸鉄ナトリウム等の鉄塩、硫酸銅，グルコン酸銅等の銅塩，硫酸亜鉛，塩化亜鉛等の亜鉛塩、酢酸マンガン等のマンガン塩，酢酸コバルト等のコバルト塩，ヨウ化カリウ

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ム，炭酸カリウム等のカリウム塩およびヨウ化物，塩化マグネシウム等のマグネシウム塩，クエン酸三ナトリウム，塩化ナトリウム等のナトリウム塩，グリセロリン酸カルシウム，炭酸カルシウム，塩化カルシウム等のカルシウム塩およびリン酸塩，リン酸一カリウム，リン酸二カリウム等のリン酸塩およびカリウム塩が使用される。ミネラル全体の使用量は2～3重量％程度である。

以上の各種組成物は均一に混合し，粉末状に調製され乳幼児用栄養組成物とされる。

本発明の乳幼児用栄養組成物は粉末状に混合調整されているので，投与時には標準で15％W／Vの濃度に水に溶解させて投与される。投与は経口投与，経腸投与のいずれでもよい。

本発明の乳幼児用栄養組成物を尿素サイクル異常患者に投与することによつて乳幼児の血中，髄液中のアンモニア濃度を低下せしめることができ，さらに栄養補給が可能となる。

また，本発明の乳幼児用栄養組成物は例えば腎不全の場合のようにたん白質摂取制限の厳しい場合でも少量のたん白質摂取で必須アミノ酸をバランス良く摂取することが可能であるために，広く栄養障害を起こした乳幼児に投与することができるものである。

次に本発明の実施例を示す。

実施例1

次に示す物質を均一に混合調製した。

カゼインナトリウム	2.243g
ホエーパウダー	3.031g
L－イソロイシン	0.157g
L－ロイシン	0.582g
L－メチオニン	0.016g
L－シスチン	0.165g
L－フェニルアラニン	0.189g
L－チロシン	0.207g
L－スレオニン	0.230g
L－トリプトファン	0.037g
L－バリン	0.275g
L－アルギニン	0.276g
L－ヒスチジン塩酸塩	0.136g

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MCT油	16.660g
植物性油	27.568g
乳糖	53.540g
ハチミツ	3.270g
ニコチン酸アミド	6.0mg
ビタミンB_1	0.91mg
ビタミンB_{12}	7.9μg
イノシット	12.49mg
ビオチン	0.06mg
dl－α－トコフエロール	6.0mg
ビタミンAとビタミンDの混合物	6.711mg
ビタミンK_1	114μg
塩酸チアミン（V．B_1）	0.72mg
塩酸ピリドキシン（V．B_6）	0.43mg
アスコルビン酸（V．C）	54.0mg
葉酸	0.24mg
パントテン酸カルシウム	2.40mg
コハク酸クエン酸鉄ナトリウム	80.0mg
ヨウ化カリウム	0.11mg
グリセロリン酸カルシウム	427.5mg

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炭酸カルシウム	565.8mg
水酸化カルシウム	414mg
塩化カルシウム二水塩	33.0mg
リン酸一カリウム	106.3mg
リン酸二カリウム	251.3mg
塩化マグネシウム六水塩	294.0mg
塩化ナトリウム	207.9mg
クエン酸三ナトリウム二水塩	44.1mg
粉末レシチン	90.0mg
シユガーエステル	225.0mg
モノグリセリド	114.0mg
硫酸銅五水塩	1.552mg
塩化亜鉛	5.13mg
酢酸マンガン四水塩	0.669mg
酢酸コバルト四水塩	0.211mg

得られた乳幼児用栄養組成物は，15％W／Vで400℃の水に溶解し，経口的又は経腸的に乳幼児に投与される。

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EXHIBIT D

US005916621A

United States Patent [19]

Georgi et al.

[11] Patent Number: 5,916,621

[45] Date of Patent: Jun. 29, 1999

[54] **THREONINE-REDUCED WHEY PROTEIN DOMINANT BABY MILK FOOD, AND PROCESS FOR MAKING SAME**

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[21] Appl. No.: **08/663,120**

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[86] PCT No.: **PCT/EP94/04209**

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PCT Pub. Date: **Jun. 29, 1995**

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[51] **Int. Cl.**[6] **A23C 9/142**; A23C 9/20; A23C 21/00

[52] **U.S. Cl.** 426/583; 426/491; 426/656; 426/801

[58] **Field of Search** 426/583, 801, 426/656, 491

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Primary Examiner—Helen Pratt
Attorney, Agent, or Firm—Bacon & Thomas

[57] **ABSTRACT**

A whey protein dominant baby food is prepared that may contain hydrolysed food with a reduced threonine content. This food can be obtained by adding glycomacropeptide-free or glycomacropeptide-reduced whey powder and/or whey protein concentrate as the whey proteins usually used in the production of milk baby food.

12 Claims, No Drawings

THREONINE-REDUCED WHEY PROTEIN DOMINANT BABY MILK FOOD, AND PROCESS FOR MAKING SAME

SPECIFICATION

The invention relates to whey protein dominant milk baby foods that may contain hydrolysed foods.

In the production of milk baby foods that may contain hydrolysed foods, among other things, cow's milk or constituents of cow's milk are used. Cow's milk proteins, for example, (caseins and whey proteins) are numbered among these. Cow's milk proteins, though, differ considerably from those of human milk. One of the essential differences exists in the ratio of casein to whey proteins. While cow's milk has a whey protein/casein ratio of approximately 20:80, in human milk, it is approximately 60:40 (50:50).

In order to be able to produce milk baby foods, which can also be called formulas, bovine whey proteins must be accordingly added to the cow's milk. Foods of this kind, which are called whey protein dominant foods, though, have the disadvantage that due to their higher threonine content in comparison to human milk, they lead to a perceptibly higher threonine level in the plasma of infants. With regard to this, please refer to the Journal of Pediatric Gastroenterology and Nutrition 1992, 14, pp. 450–455, for example.

These perceptibly increased threonine values are detected in all standard whey protein dominant formulas. But since the constituents of formulas should be adapted as much as possible to the composition of human milk, there is a need to reduce the threonine content in formulas.

Surprisingly, it has now been discovered that the analytically determined threonine contents in whey powders and whey protein concentrates that are added as whey proteins in the production of formulas, are significantly higher than the theoretically possible threonine content values that have been ascertained mathematically based on amino acid sequence data of the individual whey proteins. This led to the surprising realization that the increased threonine values in standard formulas must be due to the added whey proteins.

Consequently, the object of the present invention is to prepare a whey protein dominant milk baby food or formula with a reduced threonine content.

This object is attained by the teaching of claim 1.

Whey powder or whey protein concentrates that are used in the production of milk baby foods are obtained exclusively from sweet whey. Sweet whey is produced by precipitation of caseins from milk by using the rennet enzyme (chymosin).

In this precipitation, the kappa (κ)-casein in cow's milk is fractioned into para-κ-casein and glycomacropeptide (GMP). The para-κ-casein precipitates along with the other caseins (α-, β-, γ-caseins) of cow's milk. The GMP, however, remains in solution and consequently with the whey proteins. This means that whey powder or whey protein concentrates that are obtained from sweet whey (rennet whey) also still contain the GMP in addition to the actual whey proteins, which must in fact be taken into account with the caseins. The GMP surprisingly is now distinguished by a very high content of threonine. It has been calculated that whey proteins that contain the GMP of κ-casein contain approximately 50% more threonine than whey proteins that do not contain this GMP.

Consequently, in the production of formulas, which is known per se, the crux of the present invention is to add whey proteins or whey powder that do not contain any GMP or whose GMP content has been partially or completely removed.

If the intent is to use whey powder and whey protein concentrates obtained from sweet whey, then the residual GMP remaining in solution in the casein precipitation and consequently remaining with the whey proteins, must be partially or completely removed by means of suitable processes. This can be undertaken with the aid of ultra-filtration, for example. After the pH value of the sweet whey is adjusted to below 4.0, ultra-filtration is performed. A permeate obtained in this way contains the GMP, while the residue contains the concentrated whey proteins. In this manner, the GMP can be removed from sweet whey (rennet whey), for example, on a commercial scale; with regard to this, please refer to U.S. Pat. No. 5 075 424.

Furthermore, it is also possible according to the invention to use whey proteins obtained from sour whey. In sour whey, the caseins are precipitated with the aid of acids (mineral acids such as hydrochloric acid or sulfuric acid, or organic acids such as lactic acid that is produced with the aid of lactic acid bacteria). In this process, all caseins in cow's milk are precipitated out, including the complete casein. The sour whey consequently contains only the whey proteins, but not the GMP from the κ-casein.

Up to this point, though, whey powder or whey protein concentrate obtained from sour whey has not been used in the production of whey protein dominant milk baby foods or adapted formulas that may contain hydrolysed foods, because the processing of sour whey presents significantly greater technological difficulties than that of sweet whey. Previously, there was no reason for using whey proteins or whey protein concentrates obtained from sour whey since it was not yet known that GMP was responsible for the increased threonine content in milk baby foods of the prior art.

The subject of the invention is also a process for producing whey protein dominant milk baby foods according to claim 7, as well as the use of whey powder and/or whey protein concentrate obtained from sour whey or from GMP-free or GMP-reduced sweet whey to produce this kind of milk baby food.

With the aid of the whey protein used according to the invention, it is possible to increase the whey protein content in milk baby foods to correspond with human milk and to simultaneously reduce the threonine content to 25%.

In the production of hydrolysed foods, the whey proteins (from sour whey or from sweet whey after the removal of GMP) may be further hydrolysed with enzymes (for example trypsin and chymotrypsin) according to known processes.

According to a preferred embodiment, the threonine content of the milk baby food according to the invention is 4.0 to 5.0 g/100 g protein, preferably 4.3 to 4.8 g/100 g protein (relative to the proteins in the milk baby food). The GMP content is preferably less than 2 weight % relative to the total quantity of proteins present in the milk baby food. In contrast, whey protein dominant milk baby foods of the prior art contain from 5.2 to 6.0 g/100 g protein as well as a GMP content of more than 8%. The analytically determined fluctuations in the threonine determinations can be up to 5%.

The term "protein" or "proteins" used in the scope of the present application is understood to mean constituents made up of amino acids. The values for the content or for the quantity of protein or proteins have been determined with the aid of amino acid analysis and not on the basis of

nitrogen determination according to Kjeldahl. In the calculation of protein quantity, namely, often the nitrogen content is determined with the aid of the Kjeldahl process; the N-value obtained in this manner is then multiplied by a known factor. However, nitrogen is also detected which does not come from constituents made up of amino acids.

The invention is explained in detail in conjunction with the following examples that describe preferred embodiments.

EXAMPLE 1

Adapted Milk Baby Food as a Spray Product (batch size 100 kg)

172.2 kg cream (with 10.2% milk fat and 11.72 kg nonfat dry milk solids) are introduced into a heatable tank with an agitator and heated to 70° C. Under intensive agitation, 30.4 kg demineralized whey powder (13.5% protein) from sour whey or sweet whey after removal of the GMP, 26.9 kg lactose, 0.025 kg taurine, 0.3 kg potassium chloride (predissolved in 10 l of water at 60° C.), 0.4 kg calcium carbonate, and 0.5 kg of a mixture of minerals are added and completely dissolved in succession. 0.5 kg of emulsifier are dissolved in 11.2 kg of hot vegetable shortening mixture (50–60° C.) and added to the batch. Then, a vitamin mixture (0.5 kg) is stirred in. The finished batch is heated to 70–75° C. and homogenized at 180 bar. Then, the concentrate is heated to 95° C. by a heating device, cooled to 70° C., and spray dried.

EXAMPLE 2

Milk Baby Food Based on Hydrolysate. (batch size 100 kg)

In 100 l of hot water (approx. 70–75° C.) the following ingredients are dissolved in succession under intense agitation:

36.8 kg lactose, 14.8 kg maltodextrin, 3.0 kg starch, 7.8 kg whey protein hydrolysate (from sour whey or sweet whey after removal of the GMP), 6.5 kg casein hydrolysate, 0.09 kg reduced glutathione, 0.6 kg potassium chloride (predissolved in approx. 5 l of warm water at 60° C.), 0.27 kg tripotassium citrate (pre-dissolved in approx. 5 l of water at 60° C.), 0.19 kg citric acid (pre-dissolved in approx. 3 l of hot water at 60° C.), and 1.4 kg of a mineral mixture. 2 kg of emulsifiers are completely dissolved in hot (50–60° C.) melted fat (26.3 kg) and the mixture is added to the batch. Then, the vitamin mixture (0.31 kg) is added and completely dissolved. The batch is heated to 70–75° C. and homogenized at 180–200 bar. Then, the concentrate is heated to 95° C. in a heating device and then spray dried.

We claim:

1. A whey protein dominant milk baby food containing unhydrolyzed whey protein or hydrolyzed whey protein or a mixture thereof as a whey protein additive; said milk baby food having a threonine content from about 4.0–5.0 g/100 g of protein wherein said whey protein additive is added in the form of a powder or concentrate obtained either from sweet whey in which the protein content has been modified by the selective removal of at least a portion of the GMP therefrom or from sour whey in which the amount of protein contained therein is not reduced by removal of protein therefrom.

2. The milk baby food according to claim 1, wherein the whey powder and/or whey protein concentrate is obtained from sour whey.

3. The milk baby food according to claim 1, wherein the whey powder and/or whey protein concentrate is obtained from GMP-free or GMP-reduced sweet whey.

4. The milk baby food according to claim 1, wherein the threonine content is about 4.3 to 4.8 g/100 g of protein.

5. The milk baby food according to claim 1, characterized in that the glycomacropeptide (GMP) content is less than about 2 weight %.

6. A process for producing whey protein dominant milk baby food comprising using as the whey protein whey powder and/or whey proteins obtained either from sweet whey in which the protein content has been modified by the selective removal of at least a portion of the GMP therefrom or from sour whey in which the amount of protein contained therein is not reduced by removal of protein therefrom.

7. A process for reducing the threonine content of a whey protein dominant milk baby food, comprising substituting for whey protein usually added in production of said milk baby food one or more whey proteins selected from the group consisting of glycomacropeptide(GMP)-reduced whey powder, glycomacropeptide(GMP)-free whey powder, glycomacropeptide(GMP)-reduced whey protein concentrate, or glycomacropeptide(GMP)-free whey protein concentrate, or mixtures thereof; said whey protein being obtained from sweet whey in which the protein content has been modified by the selective removal of at least a portion of the GMP therefrom or from sour whey in which the amount of protein contained therein is not reduced by removal of protein therefrom.

8. The process according to claim 7, comprising substituting, for the whey protein usually added, whey protein obtained from sour whey.

9. The process according to claim 7, comprising substituting, for the whey protein usually added, whey protein obtained from sweet whey.

10. A process for producing whey protein dominant milk baby food comprising the steps of:

(a) obtaining sour whey from cow's milk; and

(b) adding said sour whey without the removal of protein therefrom, to a composition of said milk baby food to which whey protein has not previously been added.

11. A process for producing whey protein dominant milk baby food comprising the steps of:

(a) obtaining sweet whey from cow's milk;

(b) removing glycomacropeptide (GMP) from the sweet whey obtained in step (a) by adjusting the pH of the sweet whey to below about 4.0, and ultrafiltrating to obtain GMP-free or GMP-reduced sweet whey; and

(c) adding the GMP-free or GMP-reduced sweet whey to a composition of said milk baby food to which whey protein has not previously been added.

12. A whey protein dominant milk baby food, containing as the whey protein unhydrolyzed whey protein or hydrolyzed whey protein or a mixture thereof, wherein the improvement comprises substituting for the whey protein normally used in a whey protein dominant milk baby food, whey protein having a glycomacropeptide content of less than about 2 weight %, wherein the whey protein is either the protein of sweet whey in which the protein content has been modified by the selective removal of at least a portion of the GMP therefrom or the protein of sour whey in which the amount of protein contained therein is not reduced by removal of protein therefrom; and said whey protein dominant milk baby food has a threonine content from about 4.0–5.0 g/100 g of protein.

* * * * *